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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,896	08/31/2000	Isao Karube	195043US	1831

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EXAMINER	
CHIN, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/622,896	KARUBE ET AL.	
	Examiner	Art Unit	
	Christopher L. Chin	1641	

-- The MAILING DATE of this communication app ars on th cover sh et with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II – claims 17-25 in the reply filed on 10/27/04 is acknowledged. The traversal is on the ground(s) that the '755 patent does not show the special technical feature that links the groups set forth in the restriction requirement. Specifically, the '755 patent does not disclose a sensor chip with one or more antibodies against one or more antigens selected from a substance having a steroid skeleton, a substance for maintaining, promoting or inhibiting the physiological action of a steroid hormone, a substance for maintaining, promoting or inhibiting the physiological action of a sex hormone, and an endocrine disruptor (excluding a triazine compound). This is not found persuasive because column 7, lines 11-48, of the '755 patent teaches immobilizing antibodies specific for steroid hormones to the metal film of the disclosed surface plasmon resonance sensor for detection of steroid hormones.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-16 and 26-32 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

2. Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is vague. The body of the claim lacks a correlation step that relates the detected intensity of reflected light from the metallic thin film to the presence of antigen,

as set forth in the preamble of the claim. Line 6 of the claim recites improper Markush language. The phrase "selected from a substance" should be replaced with -- selected from the group consisting of --.

Claim 18 is vague. The claim is not clear as to how finding a shift in a disappearance angle of the reflected light is related the presence of antigen. The claim is also not clear as to what angle is considered a "disappearance angle" of the reflected light.

Claim 19 is vague and confusing. The claim is also not clear as to the function of the labeled antigen and how it is being used to detect the analyte antigen.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 17 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Attridge et al.

Attridge et al (US Patent 5,478,755) disclose a sensor and methods of assaying for the presence of a ligand in a sample by surface plasmon resonance using the disclosed sensor which involves

a) incubating the sample in contact with a specific binding partner for the ligand it is desired to detect carried on one surface of an optical structure;

b) irradiating another surface of the optical structure at a suitable angle or range of angles to the normal such that resonance and/or total internal reflection of the radiation occurs within the optical structure and/or the layer of specific binding partner; and

c) analyzing the reflected and/or generated radiation in order to determine whether, and if desired the extent to which and/or rate at which, the generated radiation and/or optical characteristics of the optical structure are altered by complex formation (cols. 1-2).

The optical structure comprises a substrate and optionally one or more layers of material interposed between the substrate and the layer of specific binding partner carried on the surface of the optical structure. Preferably, the optical structure comprises a transparent substrate coated with a thin metal layer, such as silver or gold, which metal layer is itself coated with a layer of dielectric material, such as silica (i.e. a fixing layer). A layer of antibodies is attached to the layer of dielectric material (col. 1, lines 44-54; col. 2, line 35, to col. 3, line 23, and col. 8, lines 3-11). Direct and indirect sensing assays are disclosed. The sensitivity of direct sensing assays can be conveniently estimated from the resolution of the sensor. The resolution may be defined as the ratio of the angular shift in the resonance peak for a particular change in refractive index of the medium adjacent to the metal surface to the angular half width of the reflected resonance minimum (col. 3, lines 24-44). Antigens that can be detected

include toxins and steroid hormones such as cortisol, estradiol, progesterone, etc (col. 7, lines 1-66).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Attridge et al in view of Malmqvist et al.

See above for the teachings of Attridge et al.

Attridge et al differs from the instant invention in failing to teach the use a surface plasmon sensor that has more than one detection area to detect more than one analyte in a sample.

Malmqvist et al (US Patent 5,492,840) disclose a surface plasmon resonance sensor with a sensing surface having more than one detection area to detect more than one analyte in a sample (col. 2, line 66, to col. 3, line 9). The sensor unit is made in one piece from a glass plate that has been coated with a thin film of metal, such as gold or silver. To the metal film is attached a layer of an organic polymer or hydrogel which contains functional groups for binding desired ligands. The ligands are bi- or polyfunctional. Every ligand contains an anti-f function for immobilization on the sensing

surface plus one or more bioselective functions for interaction with biomolecules in the sample solution (col. 4, lines 5-46).

It would have been obvious to one of ordinary skill in the art use the surface plasmon resonance sensor of Malmqvist et al in the method of Attridge et al because the method of Attridge et al uses a surface plasmon resonance sensor and the sensor of Malmqvist et al also provides the advantage of being able to detect more than one analyte in a given sample.

With respect to claim 18, while Attridge et al does not specifically teach measuring a shift in a disappearance angle of reflected light, it would have been obvious to one of ordinary skill in the art that such a measurement is done because Attridge et al teach measuring a ratio of the angular shift in the resonance peak for a particular change in refractive index of the medium adjacent to the metal surface to the angular half width of the reflected resonance minimum for the resolution of the sensor. The angular half width of the reflected resonance minimum appears to be the disappearance angle of the reflected light.

7. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Attridge et al in view of Buechler et al.

See above for the teachings of Attridge et al.

Attridge et al differs from the instant invention in failing to teach the detection of an endocrine disruptor having a cyclic hydrocarbon portion, such as dioxins.

Buechler et al (US Patent 5,089,391) disclose an immunoassay that can be used for the detection of dioxins (col. 29, lines 4-25).

It would have been obvious to one of ordinary skill in the art to incorporate antibodies specific for dioxins, as taught by Buechler et al, into the immunoassay method of Attridge et al because Attridge et al teaches detection of toxins in general and one would use the appropriate antibody to detect the desired toxin, such as dioxins.

Allowable Subject Matter

8. Claim 19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

WO 90/11525 disclose a displacement assay performed on a surface plasmon resonance sensor but does not teach the use of a labeled antigen as the reagent that is displaced when analyte antigen is present.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher L. Chin
Primary Examiner
Art Unit 1641

1/10/05